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June 24, 2015

United States ex rel. Bilotta v. Novartis Pharmaceuticals Corp.
No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

We represent defendant Novartis Pharmaceuticals Corporation ("NPC") in the above-captioned matter. In accordance with Paragraph 4.A of the Court's Individual Rules of Practice, we write to respond to the letter filed by plaintiff United States of America (the "U.S.") on June 19, 2015 (the "Letter"), requesting a pre-motion conference on its anticipated motion to compel.

Introduction.

As discovery has proceeded in this case, it has become evident that the Government is seeking to expand this case beyond the scope of its Amended Complaint – and is looking to use discovery as a vehicle to do so. The Government's anticipated motion to compel raises two illustrative issues:[1]

First, as the Court recognized when considering NPC's motion to dismiss, this case already involves a 10-year period, from 2002 through 2011. The Amended Complaint references the period "[f]rom 2002 through at least 2011", but it contains no allegations regarding the period post-2011, despite the fact that the Amended Complaint was filed in

[1] Federal Rule of Civil Procedure 26 ("Rule 26") allows parties to obtain discovery concerning "any nonprivileged matter that is relevant to any party's claim or defense". Fed. R. Civ. P. 26(b)(1). Consistent with the plain language of that Rule, courts have "authority to confine discovery to the claims and defenses asserted in the pleadings", and "parties . . . have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings". *Barbara v. MarineMax, Inc.*, No. 12-CV-368 (ARR) (RER), 2013 WL 1952308, at *2 (E.D.N.Y. May 10, 2013) *quoting* Fed. R. Civ. P. 26(b)(1) Advisory Committee Notes. In particular, "discovery may not be used as a fishing expedition to discover additional instances of wrongdoing beyond those already alleged" in a party's complaint. *Barbara*, 2013 WL 1952308, at *2 (quotation marks and citation omitted); *see also Haber v. ASN 50th St., LLC*, 272 F.R.D. 377, 382 (S.D.N.Y. 2011). Yet that is what the U.S. is apparently seeking to do here.

August 2013. Notwithstanding that, the U.S. now seeks discovery *for an additional 4 years – i.e.*, for the 2001 year, and for 2012 through 2014.

Second, the U.S. is seeking discovery that NPC believes is precluded by a prior Settlement Agreement reached between NPC and the U.S. dated September 29, 2010 ("Settlement", attached as Exhibit A to the U.S.'s Letter). As part of that Settlement, the U.S. released NPC from "any civil . . . claim that the United States has or may have" for specified "Covered Conduct", associated with certain drugs. Letter at Ex. A at 6. We believe that the Settlement released NPC from any liability arising from the "Covered Conduct", including liability at which plaintiffs' proposed discovery is directed. The U.S. is now taking the position in this case (1) that it should be afforded discovery into that same Covered Conduct previously released by the U.S. (through the provision of nationwide Speaker Program Data[2] and Prescription Data for those drugs for 2002-2010) in order to look for evidence to support alleged liability in the period after 2009; and (2) that certain drugs – namely the "HCT" variants of Diovan, Exforge and Tekturna – are excluded from the release, despite the fact that the Settlement stemmed from an investigation that from its inception was understood by both the U.S. and NPC to encompass those HCT variants.

NPC respectfully believes that both of the foregoing positions being taken by the U.S. are without merit, and that these attempts to expand this case, particularly through the back door of discovery, should be rejected. This case is already massive – encompassing 10 years and tens of thousands of unique individual speaker programs conducted nationwide. The U.S. should be held to its own pleadings and its prior settlement agreement with NPC, and the requested discovery should not be permitted.

Issue One: The U.S.'s Attempt to Expand the Relevant Time Period.

This case follows an investigation initiated by the U.S. in November 2011 that focused on NPC speaker programs that were conducted beginning in January 1, 2002. *See* Subpoena (Nov. 18, 2011), at 3. Consistent with the time period covered by that investigation, the Amended Complaint alleges that, "[f]rom 2002 through at least 2011", NPC conducted "sham" speaker programs as a means of "paying kickbacks to doctors" in order to induce them to write prescriptions of NPC CV-division drugs. *See, e.g.*, Am. Compl., Dkt. No. 62 ¶¶ 1-6, 71. The Amended Complaint specifically describes 269 allegedly "sham" speaker programs and roundtable events – not one of which occurred prior to 2002 or after 2011. Consistent with that, the Government's First Set of Requests for Documents and Interrogatories (the "First Set of Requests") defined the relevant "Covered Period" as commencing on "January 1, 2002".[3] *See* First Set of Requests (Sept. 20, 2013), at 3.

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[2] Capitalized terms not defined herein have the same definitions provided in the U.S.'s Letter.

[3] The First Set of Requests defined a separate "Covered Period" for Diovan, Exforge and Tekturna, which did not commence until "January 1, 2010". *See* First Set of Requests at 3. After NPC pointed out that even the U.S.'s own discovery requests did not seek materials for 2001, the Government served its Second Set of Requests for Production of Documents (the "Second Set of Requests"), seeking documents for *all* of the Covered Drugs, during the period "January 1, 2001, to December 31, 2014". *See* Second Set of Requests (May 1, 2015), at 3. That includes the Released Drugs (Diovan and Diovan HCT, Exforge and Exforge HCT, and Tekturna and Tekturna HCT) during the released time period (January 1, 2002 through December 31, 2009), and also includes four

The U.S. does not dispute that the time period explicitly referenced in its Amended Complaint is 2002 through 2011 – or that its Amended Complaint fails to identify even a single supposedly "sham" program conducted either before 2002 or after 2011. Instead, the U.S. claims that it may seek discovery over a new *14-year* time period because (1) the Amended Complaint pleads ongoing misconduct, *see* Letter at 3; (2) discovery need not be confined to the time period specifically alleged in the Amended Complaint, *see id.* at 3-4; and (3) the requested data might be used to help the U.S. "identify all doctors who participated in sham speaker programs" or to assess "trends and fluctuations" in doctors' prescription-writing, *see id.* at 4. We submit that none of those arguments justifies the U.S.'s effort to obtain this broad and burdensome discovery.

First, contrary to the U.S.'s contention, the Amended Complaint does *not* plead ongoing misconduct. The Amended Complaint discusses NPC's alleged misconduct almost exclusively in the past tense. Indeed, in a 192-paragraph complaint, the U.S. has done nothing more than insert some variation of the phrase "through at least 2011" approximately six times. *See* Am. Compl. ¶¶ 1, 71, 95, 172, 173, 178. Other courts have found such allegations insufficient to plead ongoing misconduct under the False Claims Act. *See U.S. ex rel. King v. Solvay S.A.*, CIV.A. No. H-06-2662, 2013 WL 820498, at *3-4 (S.D. Tex. Mar. 5, 2013); *U.S. ex rel. Spay v. CVS Caremark Corp.*, CIV.A. No. 09-4672, 2013 WL 4525226, at *2-3 (E.D. Pa. Aug. 27, 2013). Unsurprisingly, given the allegations in the Amended Complaint, this Court's Motion to Dismiss decision also describes the relevant time period as running from 2002 through 2011. *See* Mem. Op. and Order, Dkt. No. 110 at 41 (Sept. 30, 2014) ("The claims that are at issue here relate to prescriptions . . . that . . . were written by doctors between January 2002 and 2011".); *see also id.* at 30 ("[T]he alleged kickback scheme took place over nine years".).

Second, the U.S. is incorrect that it may obtain discovery without regard to the time period specifically alleged in the Amended Complaint. Many of the cases cited by the U.S. in support of that position were decided under the prior version of Rule 26 (which allowed discovery into any matter relevant to the "subject matter" of the case).[4] Rule 26 has since been amended to make clear that courts may exercise discretion to limit discovery to the well-pleaded allegations of a plaintiff's complaint, especially where the discovery sought is broad. *See* Fed. R. Civ. P. 26(b)(1), Advisory Committee Notes; *Barbara*, 2013 WL 1952308, at *2; *Haber*, 272 F.R.D. at 380. Courts applying the new standard – particularly in the FCA context – have concluded that the time period alleged in plaintiff's complaint is relevant for defining the proper boundaries of discovery. *See Spay*, 2013 WL 4525226, at *2-4; *Solvay*, 2013 WL 820498, at *3-4.[5]

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additional years – a 40% increase – on top of the 10-year time period specifically alleged in the Amended Complaint.

[4] *See Daval Steel Prods. v. M/V Fakredine*, 951 F.2d 1357, 1367 (2d Cir. 1991); *Abu-Nassar v. Elders Futures Inc.*, No. 88 Civ. 7906 (PKL), 1991 WL 45062, at *16 (S.D.N.Y. Mar. 28, 1991); *United States v. Int'l Bus. Machines Corp.*, 66 F.R.D. 180, 182 (S.D.N.Y. 1974), cited at Letter at 4.

[5] Furthermore, each of the cases cited by the U.S. – none of which was decided in the FCA context – is factually distinguishable. *See, e.g., Int'l Bus. Machines*, 66 F.R.D. at 185 (allowing discovery into "pre-complaint and post-complaint activities of defendant" where, among other things, plaintiff adequately pleaded "a continuing violation" of the Sherman Antitrust Act).

Third, the U.S.'s suggestion that it needs 14 years' worth of Speaker Program and Prescription Data in order "to identify all doctors who participated" in allegedly "sham" programs and/or to assess "trends" in prescription-writing is an overstatement. NPC has already given the U.S. 10 years' worth of that data (on a nationwide scale), which is more than sufficient for the U.S. to identify "doctors" and "trends".[6] What the U.S. seeks is more data than it is entitled to receive given the allegations in the Amended Complaint and the limits imposed by Rule 26. *See* Fed. R. Civ. P. 26(b)(2)(C)(iii) ("[T]he court must limit the . . . extent of discovery otherwise allowed by these rules . . . if it determines that . . . the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case".). Given the extensive data that it has received – concerning conduct taking place nationwide over 10 years – the U.S. simply does not need this additional data, which will only add to the already burdensome discovery in this case (and will only serve to further expand discovery down the road – for example, at depositions, if the U.S. intends to question witnesses on such data).

Issue Two: The U.S.'s Attempts to Ignore and/or Rewrite Its Prior Agreement with NPC.

The U.S. acknowledges that it entered into the Settlement with NPC in September 2010. *See* Letter at 1. The effect of that Settlement was that the U.S. released any and all claims that it had or might have, at any time, arising from NPC's conduct concerning Diovan and Diovan HCT, Exforge and Exforge HCT, and Tekturna and Tekturna HCT during the period 2002-2010. In pressing for broad discovery in this case, the U.S. (1) misstates the relevant language of the release, and (2) argues that not all of the Released Drugs were actually released. The U.S. is seeking to rewrite a settlement and release for which NPC paid approximately $237M.

The U.S. admits in its Letter that it seeks to use NPC's pre-2010 "Covered Conduct" (*i.e.*, hosting a speaker program and paying a doctor an honorarium) as a basis for establishing liability in the post-2010 time period. *See id.* at 4-5. However, the Settlement expressly prohibits the U.S. from doing that. The Settlement is structured around "conduct", which is defined to include the provision of "illegal remuneration, through mechanisms such as speaker programs" "[d]uring the period January 1, 2002 to December 31, 2009" and involving, among other drugs, "Diovan®, . . . Exforge®, and Tekturna®" ("Covered Conduct"). Letter at Ex. A. at 3-4. The Settlement "releases NPC . . . from *any* civil or administrative monetary *claim* that the United States has *or may have* for the Covered Conduct". *Id.* at 6-7 (emphasis added). Importantly, there is no time limitation imposed on the claims released by the Settlement; consequently, the Settlement releases *all claims* – whenever brought and covering any time period – that stem from NPC's hosting of speaker programs for Released Drugs between 2002 and 2010. For that reason, the U.S.'s contention that "[t]he 2010 Release does not shield the 2002-2009 data from use in potential litigation with respect to claims arising after the Released Period", Letter at 5, is simply not so. That is precisely what the Settlement

[6] To date, NPC has produced Speaker Program Data for Lotrel, Starlix and Valturna from January 1, 2002 through November 18, 2011, and for Diovan and Diovan HCT, Exforge and Exforge HCT, Tekturna and Tekturna HCT, and Tekamlo from January 1, 2010 through November 18, 2011. NPC has already informed the U.S. that it will produce Speaker Program Data for all of the Covered Drugs for the remainder of November 2011 and the month of December 2011. In addition, NPC has produced Prescription Data for Lotrel, Starlix and Valturna for the entirety of 2002 through 2011. NPC expects to produce Prescription Data for the remaining drugs for the entirety of 2010 through 2011, but has not yet received permission from IMS to do so.

accomplishes. The U.S.'s related argument that "[t]he 2010 Release nowhere addresses Novartis's discovery obligations" (and the cases it cites in support of that proposition), *id.*, also misses the point. As set forth above, discovery is permissible only to the extent that it seeks information that is relevant to a claim or defense in the action. Given that the Settlement released the U.S.'s claims concerning NPC's conduct involving the Released Drugs between 2002 and 2010, the Government should be precluded from asserting such claims in this case – which means they are precluded from discovery into the Covered Conduct, under Rule 26. (Notably, the Government received from NPC a great deal of information about the "Covered Conduct" during the investigation that led to the 2010 Settlement.)

Moreover, the U.S.'s contention that the HCT variants of Diovan, Exforge and Tekturna were not included in the Settlement is surprising, given the history of that settlement.[7] The Settlement stemmed from an investigation that from its inception was understood by both the U.S. and NPC to encompass the HCT variants of Diovan, Exforge and Tekturna. The parties understood that "Diovan", for example, referred to Diovan and Diovan HCT. Thus, during the course of that investigation, millions of documents were collected and reviewed, without regard to whether the document pertained to the underlying compound (*e.g.*, "Diovan") or its HCT variant (*e.g.*, "Diovan HCT") or, more commonly, both. Meetings between the U.S. and NPC at which "Diovan, Exforge and Tekturna" were discussed encompassed the HCT variants and, where appropriate, included specific references to them. Indeed, the underlying *qui tam* complaint likewise used the same collective shorthand to refer to the drugs and their HCT variants (alleging, for example, that the Diovan "franchise" was comprised of "Diovan" and "Diovan HCT" and thereafter referring only to "Diovan"). The U.S.'s effort to redefine the Released Drugs is an attempt to roll back the Settlement.[8]

At least for these reasons, NPC respectfully submits that the U.S.'s anticipated motion to compel is without merit and, if filed, should be denied.

Respectfully,

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[7] An "HCT" variant is the main compound (*e.g.*, Diovan) plus hydrochlorothiazide, which is a water pill.

[8] NPC did not separately move to dismiss claims related to those variants here, *see* Letter at 3, because it did not understand at the time that the U.S. intended to challenge the terms of the parties' Settlement.